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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Albone *et al.*

Confirmation No.: 9476

Application No.: 10/687,035

Group Art Unit: 1632

Filed: October 15, 2003

Examiner: To be Assigned

For: ANTIBODIES THAT BIND CELL-
ASSOCIATED CA 125/0772P AND
METHODS OF USE THEREOF

Attorney Docket No.: 6750-214-999

SECOND INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application. This paper is being filed pursuant to C.F.R. § 1.34.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
 - 1b. A legible copy of :
 - ☒ Each U.S. patent application publication and U.S. and foreign patent;
 - ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion;
 - ☐ all other information or portion which caused it to be listed on the PTO-1449.
 - 1c. ☒ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report.
 - 1d. ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;

- ☒ Before the mailing of the first Office action on the merits;
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114 (filed herewith).

3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(c) after the period specified in 37 C.F.R. § 1.97(b), but before the mailing date of any of a final action under 37 C.F.R. § 1.113, a notice of allowance under 37 C.F.R. § 1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. § 1.17(p) in accordance with 37 C.F.R. § 1.97(c) is:
- ☐ enclosed
- ☐ to be charged to Pennie & Edmonds LLP Deposit Account No. 16-1150.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. § 1.97(d) after the period specified in 37 C.F.R. § 1.97(c), but on or before the date of payment of the issue fee.

The \$180.00 fee set forth in 37 C.F.R. § 1.17(p) is:

☐ enclosed.

☐ to be charged to Jones Day Deposit Account No. 503013.

The Certification Statement in Item 5 below is applicable.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked)

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. § 1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. § 1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☐ This application is a continuation application under 37 C.F.R. § 1.60 or § 1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

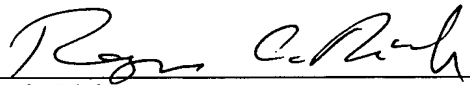
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. § 1.313(b)(5) is concurrently

filed herewith.

- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
- (Check Item 8a, 8b, or 8c)
- 8a. ☐ satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ set forth in the application.
- 8c. ☐ enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.
10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

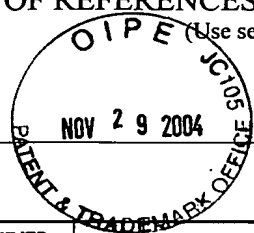
Date: NOVEMBER 29, 2004

 54,398

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LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)



ATTY DOCKET NO.

6750-214-999

APPLICATION NO

10/687,035

APPLICANT

Albone *et al.*

FILING DATE

October 15, 2003

GROUP

1632

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
B01	5,693,762	12/2/97	Queen <i>et al.</i>			

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO
B02	International Search Report of PCT/US03/32945	8/25/04	PCT			
B03	WO04005470	1/15/04	PCT			

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

B04	Andersson, <i>et al.</i> , 1999 "Biokinetics of the Monoclonal Antibodies MOv 18, OV 185 and OV 197 Labelled with ¹²⁵ I According to the m-MeATE Method or the Iodogen Method in Nude Mice with Ovarian Cancer Xenografts", <i>ACTA Oncologica</i> , 38(3) 323-328.
B05	Bouvier, <i>et al.</i> , 1988 "Serum Levels of Tumor Markers and Presence of Human Antimouse Antibodies: Implications for Diagnosis and Treatment with Radiolabeled Monoclonal Antibodies", <i>Cancer Detection and Prevention</i> , 13: 251-262.
B06	Chatal, <i>et al.</i> , 1989 "Biodistribution of Indium-111-Labeled OC 125 Monoclonal Antibody Intraperitoneally Injected Into Patients Operated On for Ovarian Carcinomas", <i>Cancer Research</i> , 49: 3087-3094.
B07	Cuesta, <i>et al.</i> , 1999 "Tissue Quantifications of CA 125 in Epithelial Ovarian Cancer", <i>The International Journal of Biological Markers</i> , 14(2): 106-114.
B08	Gaetje, <i>et al.</i> , 1999 "Ovarian Cancer Antigen CA 125 Enhances the Invasiveness of the Endometriotic Cell Line EEC 145", <i>J. Soc. Gynecol. Invest.</i> , 6(5): 278-281.
B09	Haisma, <i>et al.</i> , 1987 "Antibody-Antigen Complex Formation Following Injection of OC125 Monoclonal Antibody In Patients With Ovarian Cancer", <i>Int. J. Cancer</i> , 40: 758-762.
B10	Imai, <i>et al.</i> , 1991 "Monoclonal Antibodies Against CA125-Bearing Antigenic Molecule Fragments; reactivity with Mucinous Ovarian Tumours and Lung Cancers", <i>Molecular and Cellular Probes</i> , 5: 55-63.
B11	Kalofonos, <i>et al.</i> , 1999 "Radioimmunosintigraphy In Patients With Ovarian Cancer", <i>ACTA Oncologica</i> , 38(5): 629-634.
B12	Kobayashi <i>et al.</i> , 1993 "A Human/Mouse Chimeric Monoclonal Antibody Against CA125 for Radioimmunoimaging of Ovarian Cancer", <i>Cancer Immunol. Immunother.</i> , 37: 143-149.
B13	Markman, Maurie 1997, "The Role of CA-125 in the Management of Ovarian Cancer", <i>The Oncologist</i> , 2: 6-9.
B14	Maher, <i>et al.</i> , 1992 "Human Antibody Response to the Intravenous and Intraperitoneal Administration of the F(ab) ₂ Fragment of the OC125 Murine Monoclonal Antibody", <i>Journal of Immunotherapy</i> , 11:56-66.
B15	National Comprehensive Cancer Network Practice Guideline sin Oncology Version 1 2002 "Ovarian cancer Guideline"
B16	Nyhus, <i>et al.</i> , 2001 "IgG-Recognizing Shed Tumor-Associated Antigens Can Promote Tumor Invasion and Metastasis", <i>Cancer Immunol. Immunother.</i> , 50: 361-372.
B17	Osmer, <i>et al.</i> , 1997 "Does an Immunosintigraphy With OC 125 Affect the Prognosis of Ovarian Cancer", <i>Eur J. Gynaecol. Oncol.</i> , 18(3): 177-182.
B18	Pimm, <i>et al.</i> 1995 "Circulating Antigen: Bad or Good for Immunosintigraphy?" <i>Nucl Med. Biol.</i> , 22(2): 137-145
B19	Reinartz, <i>et al.</i> , 2000 "Immunological Properties of a Single-Chain Fragment of the Anti-Idiotypic Antibody ACA125", <i>Cancer Immunol. Immunother.</i> , 49: 186-192.
B20	Reinsberg, <i>et al.</i> , 1994 "False Changes in CA125 Levels In Ovarian Cancer Patients After Infusion of OC 125 Fragments For Diagnostic and Therapeutic Purpose", <i>Arch Gynecol Obstet.</i> , 255: 9-18.

	B21	Rustin, <i>et al.</i> , 2004 "Use of CA-125 In Clinical Trial Evaluation of New Therapeutic Drugs For Ovarian Cancer", <i>Clinical Cancer Research</i> , 10: 3919-3926.
	B22	Seelenmeyer, <i>et al.</i> , 2002 "The Cancer Antigen CA125 Represents A Novel Counter Receptor For Galectin-1" <i>Journal of Cell Science</i> , 116(7): 1305-1318.
	B23	Zeimet, <i>et al.</i> , 1997 "Modulation of CA-125 Release By Inflammatory Cytokines In Human Peritoneal Mesothelial and Ovarian Cancer Cells", <i>Anticancer Research</i> , 17: 3129-3132.

EXAMINER	DATE CONSIDERED
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	